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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,542	11/12/2003	Linda S. Powers	13368.0001 (DIV. II)	6889

7590

04/07/2005

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/706,542

Applicant(s)

POWERS ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 4-7 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8 and 10-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11-12-03.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group II (methods for taxonomic identification of a virus), invention (iv) (wherein the ligand is a peptide specific to an outer membrane protein), and species (a) (wherein the separation of the bound and excess ligand is through chromatography) in the reply filed on January 7, 2005 is acknowledged.
2. Claims 4-7, and 9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 7, 2005.
3. Currently, claims 1-3, 8, and 10-13 are under consideration.

### ***Information Disclosure Statement***

4. The information disclosure statement (IDS) submitted on November 12, 2003, is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

### ***Specification***

5. Applicants claim for priority to prior application 09/999159 is noted.

Where an applicant desires priority under 35 U.S.C. 120 to a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship

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(i.e., continuation, divisional, or continuation-in-part) of the applications. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If the parent application has become a patent, the expression “now Patent No. \_\_\_\_\_” should follow the filing date of the parent application. If a parent application has become abandoned, the expression “now abandoned” should follow the filing date of the parent application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet.

It is requested that the Applicant amend the specification to reflect that fact that the prior application 09/999159 has been issued as patent number 6,780,602.

### *Claim Rejections - 35 USC § 102*

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1 and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Piran et al. (U.S. 5,705,338). The rejected claims describe a method for the identification of a biological analyte comprising binding the analyte with a ligand conjugated to a label, separating the bound analyte from excess marker-conjugated ligands, and detecting the presence of the bound analyte.

Piran teaches a method for the determination of an analyte in a sample comprising exposing the analyte to a labeled ligand, separating the bound analyte from the excess ligand,

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and detecting the label conjugated to the ligand. See e.g., claim 1. The reference teaches that the label may be radiochemical, luminescent, or fluorescent in nature. Col. 7, lines 15-18. The reference therefore anticipates the indicated claims.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1, 3, and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Piran as applied to claims 1 and 10-12 above. The claims have been described, except that claim 3 requires that the separation step comprise the use of chromatography. The teachings of Piran have been described in part above. In addition to the teachings indicated above, the reference also teaches that the separation of the bound ligand from the unbound ligand may be performed using chromatographic methods. Column 3, lines 40-43. It would therefore have been obvious to those in the art to have used such a method to separate the bound ligand from the unbound ligand prior to the detection step.

10. Claims 2 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Piran as applied to claims 1, 3, and 10-12 above, and further in view of Powers et al. (WO 98/49557). Claims 2 and 8 further limit the method of claim 1, respectively, to embodiments wherein the

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analyte is a virus, and wherein the ligand is a peptide specific for an outer membrane protein of the virus. The teachings of Piran have been described above. While the reference teaches methods for the detection or identification of an analyte, the reference does not specify the form of the ligand or the types of analytes that may be detected.

Powers teaches methods for the identification of microorganisms. Similarly to the methods of Piran, the Powers reference teaches the use of ligands to the target analyte such that it may be identified. Further, the reference teaches that the ligand used may be a peptide that binds to proteins of the outer membrane of microbe, and where the analyte is a virus. See, pages 6-11, and claim 11. From these teachings, it would have been obvious that the peptides and viruses are functional equivalents of the ligands and analytes of Piran. It would therefore have been obvious to those in the art to modify the method of Piran for the detection of viral particles using as a ligand a peptide that binds to a protein on the surface of the viral particle. The combined teachings of the references would therefore render the claimed inventions obvious.

11. Claims 1-3, and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rothschild et al. (U.S. 5,948,624- of record in the November 2003 IDS). The rejected claims describe a method for the identification of a biological analyte comprising binding the analyte with a ligand conjugated to a label, separating the bound analyte from excess marker-conjugated ligands, and detecting the presence of the bound analyte.

Rothschild teaches methods and compositions for the detection, isolation, and identification of targets. Abstract, columns 14-15 (esp. column 15, lines 59-65). The reference teaches the use of a ligand (target substrate or substrate in the patent) conjugated to a detectable

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label for the identification of the target. Column 14, lines 31-65. Among the targets that the reference teaches may be identified through use of these conjugates are virus particles. Columns 15-16. The reference teaches that ligand may be a protein or peptide that binds to the target (column 23) and that the label may be luminescence, fluorescent, or phosphorescent (col. 2, lines 3648). Additionally, the reference also teaches that radioactive labels are known in the art. Columns 1-2. While the reference teaches that such labels certain disadvantages, such do not render the use of such labels non-obvious. The reference therefore renders obvious the use of a ligand specific for an analyte, wherein the label is conjugated to a marker, for the identification of the analyte.

The reference additionally teaches methods of using such ligands for the detection of the analytes. See e.g., column 12 lines 14-39, and column 27, lines 24-65. The methods include the steps of exposing a sample containing the analyte to the ligand, separating the bound ligand from the solution, and detecting the analyte through detection of the marker-conjugated ligand. Further, the reference teaches that chromatography methods may be used for the separation of bound analyte from unbound analyte. Column 27, lines 30-54. The reference therefore renders the claimed method obvious.

12. Claims 1-3, 8, and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rothschild in view of Powers (*supra*). Claims 1-3 and 10-13 have been described above. Claim 8 further limits the methods to embodiments wherein the ligand is peptide specific for an outer membrane protein of the virus to be detected. The teachings of Rothschild have been described

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above. While the reference teaches a method as in claim 1, the reference does not teach the use of peptides specific for an outer membrane protein of the virus as the ligand.

The Powers reference also teaches methods for the identification of microorganisms. Like the Rothschild reference, Powers teaches the use of ligands to the target analyte. Among the ligands taught by the reference are those that bind to proteins of the outer membrane of microbial cells. See, pages 6-11. In view of these teachings, it would have been obvious to those in the art that the peptides of Powers could be used as the peptide ligands suggested in the Rothschild reference. This is because both the Powers and Rothschild references use similar mechanisms for analyte detection, thus making it clear that the peptide ligands of Powers are functional equivalents to the peptide ligands of Rothschild. Because the Powers reference indicates that the peptide ligands may be used to detect a virus, those in the art would have had a reasonable expectation of success in the use of the peptides of Powers in the method of Rothschild. The combined teachings of these references therefore render the claimed methods obvious.

### ***Double Patenting***

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).



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14. Claims 1, 2, 8, and 10-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 6, 9-23, 27, and 31-41 of U.S. Patent No. 6,780,602. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent represent a species of the presently claimed invention, and would anticipate the claims of the present application is applied as prior art. Because the current claim is generic to the claims of the patent, it is rejected for obviousness type double patenting.

15. Claim 1, 2, 4, 10-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of copending Application No. 10/706,543. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application read on overlapping subject matter that would have anticipated the present claim if applicable as prior art. Because the current claim is generic to the claims of the patent, and limitations in the present claims not described in the copending claims are disclosed in those portions of the copending application providing support for that claim, the present claims are rejected for obviousness type double patenting.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 1, 2, 8, 10-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 21 copending Application

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No. 10/706,547. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application read on overlapping subject matter that would have anticipated the present claim if applicable as prior art. Because the claim of the copending application is generic to the claims of the patent, and limitations in the present claims not described in the copending claims are disclosed in those portions of the copending application providing support for that claim, the present claims are rejected for obviousness type double patenting.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

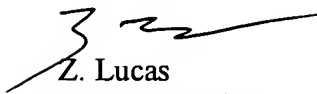
17. No claims are allowed.

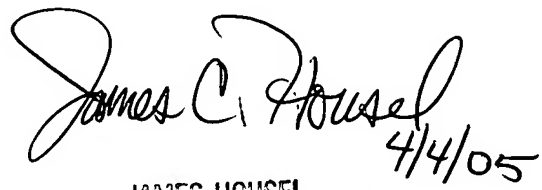
18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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